AUG 1 4 2002

K021635

510(k) SUMMARY

[As required by 21 CFR 807.87(h)]

Identification of Submitter

Submitter: William Skremsky
Senior Regulatory Affairs Specialist
CTI PET Systems, Inc.
810 Innovation Drive
Knoxville, TN 37932

Telephone No: (865) 218-2522
Fax No: (865) 218-3000

Date of preparation: May 10, 2002

Identification of the Product

Device Proprietary Name: ECAT Vision 3000 and ECAT Vision 5000
Common Name: Positron Emission Tomography (PET) Scanner
Classification Name: Emission Computed Tomography System per 21 CFR 892.1200

Marketed Devices to Which Equivalence is Claimed

Device	Manufacturer	510(k) Number
ECAT EXACT	CTI PET Systems (CPS)	K962797
E.CAM LSO 311	CTI PET Systems (CPS)	K981027
ECAT PET/CT	CTI PET Systems (CPS)	K002715

Device Description

The ECAT Vision 3000 and Vision 5000 are new positron emission tomography (PET) scanner systems. The ECAT Vision series PET scanners utilize rotating flat panel detector heads, LSO crystal detector technology and coincidence point source transmission scan capability. The ECAT Vision series scanners are produced and marketed under two distinct models, the ECAT Vision 3000 and the ECAT Vision 5000. The two models of the ECAT Vision are configured with either: 1) three detector heads in the ECAT Vision 3000, or 2) five detector heads in the ECAT Vision 5000.

A Patient Handling System (PHS) is provided with the Vision series scanners, which is a slightly modified version of the PHS included with the CPS ECAT EXACT series PET scanners (K962797). Vertical bed travel, horizontal scanning range and all other PHS operating characteristics are the same for the PHS provided with the Vision series scanners as those of the PHS provided with the ECAT EXACT series scanners. The maximum patient weight specification for the Vision series PHS, is 182 kg (400 lbs).

The acquisition computer system is an ACS III system, similar to that used for the ECAT PET/CT system (K002715). Image reconstruction for the ECAT Vision scanners is performed using a dedicated reconstruction computer. The reconstruction algorithm is FOREJ rebinning and 2D

Attenuation Normalization Weighted OSEM (ANW-OSEM). The reconstruction system interfaces with the acquisition raid disk system for access to the basic acquired data.

The operating console computer is an updated version of the existing ECAT PET/CT operating console. The console runs Siemens Syngo software, with CPS ECAT PET acquisition and application software overlaying the Siemens software. This computer is based on an Intel Pentium system running Microsoft's Windows 2000, or later, operating system. Operating in a *syngo*-based, NT environment, the ECAT Vision operating software provides acquisition, display, diagnostic, application, system, archival, and retrieval support capabilities. Initially, whole-body oncology applications and visualization tools are being provided.

Indications for Use

The CPS/Siemens ECAT Vision 3000 and Vision 5000 PET systems are positron emission tomography (PET) scanners that are intended to be utilized by appropriately trained health care professionals to image and measure the distribution of injected positron emitting radiopharmaceuticals in humans for the purpose of determining various metabolic and physiologic functions within the human body.

Comparison with Predicate Devices

The ECAT Vision series PET scanners leverage much of the already proven technology, as well as many components and features of currently produced CPS tomographic systems. The flat panel detectors, LSO crystal detector technology, and coincidence point source transmission scanning design concepts were borrowed from the E.CAM LSO 311 PET/SPECT system (K981027). The patient handling system (PHS) provided with ECAT Vision scanners is a slightly modified version of the PHS used on the CPS ECAT EXACT and ECAT EXACT HR+ PET systems (K962797). The Advanced Computational System (ACS III), used to store and process acquired PET data into sinograms, as well as the reconstruction computer, control console, and the ECAT PET/*syngo* software are updated versions of those components used in the ECAT PET/CT system (K002715).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 4 2002

Mr. William Skremsky
Senior Regulatory Affairs Specialist
CTI, Inc.
810 Innovation Drive
KNOXVILLE TN 37932

Re: K021633
Trade/Device Name: ECAT Vision PET Scanner
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: May 10, 2002
Received: May 17, 2002

Dear Mr. Skremsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K021633

Device Name: ECAT Vision PET Scanner

Indications for Use:

CPS ECAT Vision 3000 and ECAT Vision 5000 positron emission tomography (PET) scanners are intended to be utilized by appropriately trained health care professionals to detect the location and distribution of injected positron-emitting radionuclides in the body and produce cross- sectional images through computer reconstruction of the data.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David G. Hegarty

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021633